

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION,

THIS DOCUMENT RELATES TO ALL
ACTIONS

MDL NO. 1456

Civil Action: 01-CV-12257-PBS

Judge Patti B. Saris

Chief Magistrate Judge Marianne B. Bowler

**DEY, INC.'S AND ABBOTT LABORATORIES' OBJECTIONS TO
THE ORDER OF CHIEF MAGISTRATE JUDGE BOWLER ISSUED
ON FEBRUARY 4, 2006 PURSUANT TO FED. R. CIV. P. RULE 72(a)**

Dey, Inc. ("Dey") and Abbott Laboratories ("Abbott") respectfully submit the following objections to the Order of Chief Magistrate Judge Bowler issued on February 4, 2006 (the "Order") after a hearing on February 2, 2006, concerning the motions for protective order filed by Fallon Community Health Plan, Inc. ("Fallon"), Tufts Associated Health Plans, Inc. ("Tufts") and Neighborhood Health Plan, Inc. ("NHP") and the objections filed by Harvard Pilgrim Health Plan ("HPHC") (collectively the "Massachusetts Payors"). Chief Magistrate Bowler's Order also granted the Motion for Protective Order filed by Plaintiffs.

Preliminary Statement

Chief Magistrate Bowler's rulings are clearly erroneous and incorrect as a matter of law. Her findings contradict this Court's prior rulings regarding health insurer discovery, which have consistently ordered such discovery to proceed notwithstanding assertions by third-parties -- similar to the assertions of the Massachusetts Payors here -- that such discovery would be unduly burdensome. On numerous occasions, this Court has recognized the significance of health insurer discovery which Defendants cannot obtain from representative Plaintiffs and is necessary

to defend against Plaintiffs' claims. Here, Chief Magistrate Bowler has made an about-face even though the Massachusetts Payors' purported concerns about burden and confidentiality are no different from those previously raised and rejected.

Defendants seek discovery from the Massachusetts Payors that is substantially similar to the discovery previously ordered to be produced from a number of other health plans. The Massachusetts Payors make no argument that would credibly distinguish them from the many other health insurers who have already complied with discovery in this action without suffering any undue burden and without jeopardizing their confidential and proprietary information. Discovery sought from the Massachusetts Payors is clearly highly relevant, particularly because these entities fit squarely within this Court's Massachusetts class definition. And yet, Chief Magistrate Bowler has erroneously found that the Massachusetts Payors' burden claims and confidentiality concerns are categorically different from those that have been raised and rejected before. For the reasons discussed below, Chief Magistrate Bowler's order should be overturned.

Procedural Background

On August 16, 2005, the Court certified, among other classes, a class of Massachusetts third-party payors and consumers who paid for physician-administered drugs where reimbursement was based explicitly on average wholesale price ("AWP"). *In re Pharmaceutical Indus. Average Whole Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005). Having received a clear description of the Plaintiffs' third-party payor class, i.e., third-party payors doing business in Massachusetts, and nearing the close of Track 2 discovery, Defendants Dey and Abbott served subpoenas for documents and depositions (the "Massachusetts Discovery") on four selected Massachusetts Payors. The Massachusetts Discovery was substantially identical to subpoenas

served on other health insurers and approved by this Court¹. Tufts was served on November 9, 2005, NHP was served on November 10, 2005, Fallon was served on November 22, 2005 and HPHC was served on November 23, 2005. (Exhibits A through D).² In response, Tufts filed a Motion for Protective Order on November 25, 2005, and NHP and Fallon filed similar motions on November 29, 2005 and January 27, 2006 respectively. On January 5, 2006, HPHC submitted its objections, in letter format, to the subpoena served on HPHC by Abbott. (Hereinafter the motions and objections are collectively referred to as the “Motions.”) Similar themes were repeated in the Motions--that the document requests were unduly burdensome and that they would result in disclosure of proprietary information to potential competitors.

On February 2, 2006, Chief Magistrate Bowler considered the Motions filed by the Massachusetts Payors and granted them. Plaintiffs also filed a Motion For Protective Order concerning the Massachusetts Discovery which was granted. The only written order issued to date is the notation on the docket that states that the Tufts Motion for a Protective Order was granted, NHP’s Motion for a Protective Order was granted, Fallon’s Motion for a Protective Order was granted and Plaintiffs’ Motion for a Protective Order was granted. During the hearing, when stating the grounds for her ruling, Chief Magistrate Bowler expressed concern for the burden that the gathering and production of documents might inflict on the Massachusetts Payors and suggested there may be some difficulty protecting proprietary information which might be called for by the subpoenas.³ The concerns regarding this disclosure appear to be centered on Blue Cross Blue Shield of Massachusetts being named as a class representative for

¹ The subpoena served on HPHC, in addition to including requests that followed up on a previously served subpoena on this entity, sought certain additional narrow categories of documents that followed up on previously sought information.

² All exhibits referenced herein are annexed to the supporting declaration of Christopher C. Palermo, dated February 16, 2006.

³ To date, we have not received a transcript of the hearing. When the transcript becomes available, we will supplement our objections.

the Massachusetts third-party payor class, as she stated that the entry of Blue Cross Blue Shield of Massachusetts changes things.

Dey and Abbott respectfully object to the Order of Chief Magistrate Bowler for the following reasons: (1) Chief Magistrate Bowler failed to consider the relevancy of the documents sought by Dey and Abbott, as required under Rule 26(a); (2) the denial of discovery is clearly erroneous as it precludes the gathering of the very type of discovery that has been deemed appropriate in a number of previous rulings, despite the fact that the Massachusetts Payors' protestations of burden were similar to numerous third party payor claims of undue burden that the Court had previously considered and rejected; (3) any concerns that the Order was necessary to keep proprietary information confidential were clearly erroneous because any proprietary information produced in response to these subpoenas would have been fully protected from disclosure to competitors by the Protective Order currently in place in this litigation; and (4) Chief Magistrate Bowler granted Plaintiffs' Motion for Protective Order without any reasoning.

Argument

Federal Rule of Civil Procedure 72 provides that a party may serve and file objections to the written order of a Magistrate Judge within 10 days of being served with a copy of the magistrate judge's order. Fed. R. Civ. P. 72(a). Once a party preserves its rights in this manner, the district judge can set aside the magistrate's order if it is found to be "clearly erroneous or contrary to law." *Pagano v. Frank*, 983 F.2d 343, 346 (1st Cir. 1993).

Chief Magistrate Bowler failed to engage in any balancing between the alleged burden of the proposed discovery sought and its likely benefit and, as a result, did not consider the relevance of the information sought from the Massachusetts Payors in light of the class certified by this Court, the allegations of Plaintiffs' Complaint and the theories of causation and damages

espoused by the Plaintiffs. Furthermore, Chief Magistrate Bowler's findings are inconsistent with previous findings concerning the relevancy of health insurer discovery, and the Order precludes the Defendants from collecting discovery similar to discovery that has previously been deemed appropriate and not unduly burdensome. The ruling also improperly accepted the Massachusetts Payors' purported confidentiality concerns about the disclosure of proprietary information to one of their competitors, even though any such concerns are fully addressed by the existing protective orders in this action. Finally, the Order granted Plaintiffs' motion without any explanation. These ruling are "clearly erroneous" and "contrary to law." The protective orders sought in the Massachusetts Payors' Motions and the Plaintiffs' Motion should be overruled and the Massachusetts Payors should be ordered to produce the discovery requested in the subpoenas served on them by Dey and Abbott.

I. Chief Magistrate Bowler's order is contrary to law because it failed to balance the burden of the proposed discovery sought with its likely benefit.

In its entirety, Rule 26 vests the court with broad discretion to administer the discovery process. *See* Fed. R. Civ. P. 26. Specifically, the rule allows the trial judge to limit discovery if the "burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(a)(2)(iii). *see In re: Sealed Case (Medical Records)*, 381 F.3d 1205, 1215 (D.C.Cir. 2004) (*citing Laxalt v. McClatchy*, 809 F.2d 885, 890 (D.C.Cir. 1987); *see also United States v. Microsoft Corp.*, 165 F.3d 952, 960 (D.C.Cir. 1999)). In performing this balancing test required by Rule 26, a court must take into account the needs of the case, the importance of the issues at stake and the importance of the proposed discovery in resolving the litigation. *In re: Sealed Case (Medical Records)* at 1215. Chief Magistrate Bowler failed to engage in this substantive balancing of the benefits of discovery against their purported burden, and accepted the assertions

of burden made by the Massachusetts Payors, even though those assertions were similar to claims of undue burden previously made by other third-party payors and rejected by the Court.

Indeed, the benefit of the Massachusetts Discovery far outweighs the burden imposed by it. This Court's class certification order put the Massachusetts Payors squarely within Classes 2 and 3, both of which are limited to Massachusetts. *In re Pharmaceutical Indus. Average Whole Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005). The health insurer discovery taken to date relates to third-party payors largely outside of Massachusetts and all types of drugs, with an emphasis on self-administered drugs (which, before this Court's class certification order, was the thrust of Plaintiffs' case). The discovery requests at issue here are targeted to class members and have been narrowed during the negotiation process to the specific drugs identified by this Court as in issue.

Furthermore, the importance of this discovery to this litigation is well known to this Court. Plaintiffs bring this action against most of the major pharmaceutical manufacturers in the country, seeking hundreds millions of dollars in damages from Defendants based on allegations that the manufacturers perpetrated a fraud on third-party payors, among others, for more than a decade. Whether the Massachusetts Payors knew that AWP did not equal acquisition cost and the extent of the difference between AWP and acquisition cost bears directly on the Plaintiffs' fraud allegations, and goes to the heart of Plaintiffs' claims. Consistent with testimony obtained from other third-party payors, Defendants fully expect the Massachusetts Discovery to show that the Massachusetts Payors knew that AWP did not equal acquisition cost and that they set their reimbursement levels based on negotiations with providers, not on any price reported by the manufacturers. Defendants believe that at least some of the Massachusetts Payors also purchased the relevant drugs directly from the Defendants. If that is the case, any such

Massachusetts Payors would be fully aware of the acquisition cost of these drugs, further negating any fraud claim made by Plaintiffs.

Finally, the Massachusetts Discovery is vital to the resolution of this case and likely dispositive of Plaintiffs' theory of causation and damages. Plaintiffs have suggested that liability and damages can be determined based on payors' "expectations" of AWP and acquisition cost. If, as Defendants anticipate, the Massachusetts Payors expected a difference between AWP and acquisition cost, and reimbursed in relation to AWP anyway, then Plaintiffs' theory of causation and damages is contradicted by the evidence. Indeed, the Massachusetts Discovery is focused specifically on unmasking third-party payors' expectations and demonstrating the lack of support for Plaintiffs' expectation theory.

Under the required balancing test, the benefit of discovery outweighed the asserted burden, and the discovery sought from the Massachusetts Payors should proceed.

II. Chief Magistrate Bowler's denial of the Massachusetts Discovery is clearly erroneous as it precludes the gathering of the same type of discovery that has been deemed appropriate in previous rulings, in the face of similar assertions of undue burden.

Chief Magistrate Bowler has previously rejected claims of confidentiality and similar claims of undue burden by other third-party payors and compelled payors to produce documents similar to those requested in the subpoenas at issue here:

- On April 26, 2004, Plaintiffs' Motion For Protective Order to Putative Class Members was denied. Plaintiffs sought the protective order on the grounds that Defendants were not entitled to absent class member discovery and seeking such discovery would cause undue burden. (Exhibit E).
- On November 2, 2004, Chief Magistrate Bowler denied a Motion to Quash by Aetna, Humana, and CIGNA. Among other things, these third-party payors

argued, just as the Massachusetts Payors argue here, that the subpoenas were unduly burdensome. (Exhibit F).

- On January 27 2005, Chief Magistrate Bowler granted Defendants' Motion to Compel against Health Net. Health Net argued that its data and documents were confidential and that the production would cause an undue burden. (Exhibit G).
- On November 9, 2005, Chief Magistrate Bowler denied a Motion for Protective Order by six Blue Cross Blue Shield Plans, which argued that Defendants had obtained sufficient health insurer discovery and that the collection of the discovery would cause an undue burden on the plans. (Exhibit H).
- On the very day of the rulings at issue here, Chief Magistrate Bowler granted motions to compel against United Health Care and Empire Blue Cross Blue Shield, flatly rejecting any burden claims made by both entities.

Chief Magistrate Bowler has rejected all of the burden and confidentiality claims made by these different third-party payors, and all of these payors have gone on to produce documents with no apparent undue burden. The Massachusetts Payors made arguments similar to these health insurers, failing to provide any significant distinction between themselves and the other payors that have previously complied with discovery. The fact that numerous other health insurers - including some small plans such as Blue Cross Blue Shield of Hawaii and Mutual of Omaha, among others -- have been able to comply with subpoenas seeking similar information belies the Massachusetts Payors' protestations that compliance with the subpoenas at issue would impose severe hardship upon them. Consequently, there was no reason for this Court to distinguish the Massachusetts Payors from those that have previously responded to discovery. It is clear error for Chief Magistrate Bowler to deny Defendants any discovery whatsoever from the

Massachusetts Payors when there is no reasonable basis to believe that such discovery would be any more burdensome to the Massachusetts Payors than it has been to the numerous other payors that have already complied with similar discovery requests. Moreover, to the extent that Chief Magistrate Bowler concluded that there was a reasonable basis to distinguish the Massachusetts Payors from the many other payors who have been required to comply with discovery in this action, the Court should have narrowed the discovery sought from the Massachusetts Payors to address any legitimate claims of excessive burdens, rather than flatly denying all discovery against the Massachusetts Payors on a blanket basis.⁴ Dey and Abbott had both indicated their willingness to work with the Massachusetts Payors to attempt to address any legitimate concerns relating to burden and expense.

III. Any proprietary information produced as part of these subpoenas is protected by the Protective Order implemented by this Court.

Chief Magistrate Bowler's concerns about protecting proprietary information produced by the Massachusetts Payors are unfounded. Moreover, the suggestion that the naming of Blue Cross Blue Shield of Massachusetts as a class representative somehow changes things reflects a misunderstanding of the Protective Order in place. The Protective Order entered by this Court on December 13, 2002 specifically protects against disclosure of proprietary information to an entity's competitors (whether or not the competitor is a party to the action) by limiting the persons with whom any proprietary information can be shared and the purpose for which the information can be used. The proprietary information for which the Massachusetts Payors seek protection can be designated "highly confidential" and therefore afforded the maximum protection under the protective order. With such a designation, the protective order limits disclosure of the information to in-house counsel (with additional limitations as to the location at

⁴ Indeed, Neighborhood agreed, after filing its motion that it could produce certain categories of documents in response to the subpoena, implicitly conceding that doing so would not entail an undue burden.

which in-house counsel may view the information), outside counsel, court personnel, experts and consultants, and, during a deposition, current employees of the entity that produced the applicable documents. Protective Order ¶6. Therefore, information that the Massachusetts Payors opt to designate as “highly confidential” would not be disclosed to Blue Cross Blue Shield of Massachusetts or any other parties. The protective order also limits the use or disclosure of this information to this litigation *only*, and expressly precludes the use of confidential or highly confidential information for any business purposes, or in any other litigation or other proceeding, or for any other purpose. Protective Order ¶8.

Further, the protective order expressly extends protections to persons or entities who are not parties in the litigation. Protective Order ¶22. The protective order also allows this Court, at the request of a producing party, to bar persons who are not permitted access to the protected information from attending any hearing or deposition at which such information is revealed. Protective Order ¶16. Additionally, the protective order has specific requirements for the handling of this information by attorneys and experts following the final termination of this action. Protective Order ¶24. All of these safeguards, taken together, provide more than adequate protection to the Massachusetts Payors, while providing Defendants with the information necessary to defend the claims against them.

The protective order has provided Defendants with sufficient protection against the disclosure of competitive commercially-sensitive information to their codefendants in this case, even where those codefendants are direct competitors with respect to certain drugs, and would likewise provide more than adequate protection to any health insurer. The Massachusetts Payors suggested that because they all compete for the same customers in Massachusetts they should not

be forced to reveal this proprietary information. The protective order, however, takes that concern into account by the extensive safeguards outlined above.

The fact that Blue Cross Blue Shield of Massachusetts is now a class representative does not create confidentiality concerns because “highly confidential” information cannot be disclosed to parties. In this case, Defendants are all pharmaceutical manufacturers who compete with one another for the same customers and have had their competitive pricing information disclosed in this litigation. Defendants have a strong incentive to see that the protective order is adequate and have found it to be sufficient. Just like Defendants, the Massachusetts Payors’ confidential information would be adequately protected from disclosure to their competitors by the protective order, and it was error for Magistrate Bowler to find differently.

IV. Chief Magistrate Bowler granted the Plaintiffs’ Motion For Protective Order without explanation.

In the Order, Chief Magistrate Bowler granted Plaintiffs’ Motion For Protective Order but failed to describe the basis for that ruling. Chief Magistrate Bowler expressed concern for the confidentiality of the Massachusetts Payors’ documents, and for the burden these subpoenas might impose on the Massachusetts Payors, but did not address any of Plaintiffs’ arguments. Specifically, Plaintiffs raise four unrelated grounds for seeking to quash the Massachusetts discovery. Plaintiffs suggest that there has been an insufficient showing of justification for the Massachusetts Discovery. To the contrary, as discussed above in Section II, the Massachusetts Discovery is highly relevant. Second, Plaintiffs suggest that the Massachusetts Discovery has been obtained from other sources. This cannot be the case because other health insurer discovery has not focused on Massachusetts insurers. This Court’s recent class certification order places the Massachusetts Payors squarely within the class definition, a position other health insurers have not occupied. Although the Defendants are now obtaining discovery from Blue Cross Blue

Shield of Massachusetts, Defendants' discovery concerning the knowledge of the Massachusetts classes that have been certified should not be limited to discovery from a single plan that is by far the largest plan in Massachusetts. Discovery from a number of smaller Massachusetts plans, as sought here, is highly relevant to the critical issue of the extent of the class's knowledge, and Defendants should be permitted to proceed with such discovery .

Plaintiffs also suggest that the Massachusetts Discovery was served by Dey and Abbott in an attempt to circumvent the Track 1 discovery deadline. Plaintiffs' argument is meritless. Simply because Track 1 Defendants have engaged in similar discovery does not mean that Track 2 Defendants cannot also engage in health insurer discovery, particularly when such discovery is focused on the Massachusetts class that this Court has now certified. Defendants, not Plaintiffs, are in the best position to determine their discovery needs and should be allowed to do so. Moreover, Defendants are entitled to discovery concerning all of the drugs at issue in the litigation, both because they are entitled to explore whether reimbursement for some drugs cross-subsidizes reimbursement for other drugs, and so they can understand how the total patient procedure (both the drug and service components) are reimbursed. Finally, Plaintiffs argued that the deposition notices accompanying the subpoenas to Fallon and HPHC failed to provide adequate notice. With respect to Fallon, Defendant Dey agreed to change the proposed deposition date in the subpoena to December 21, 2005 - thereby providing more than 21 days notice - and further offered to agree on a mutually acceptable deposition date if the proposed date was unacceptable to Fallon. As a result, Fallon suffered no prejudice from the deposition date noticed in the initial subpoena. Similarly, Defendant Abbott agreed to postpone the scheduling of any deposition of HPHC until HPHC had completed its production.

Chief Magistrate Bowler's ruling on Plaintiffs' motion was clearly erroneous because it did not directly address any of the issues raised by Plaintiffs, yet amounted to a wholesale granting of Plaintiffs' motion.

CONCLUSION

For the foregoing reasons, Chief Magistrate Bowler's order should be overturned and the Massachusetts Payors should be required to respond to the subpoenas served on them by Defendants.

Dated: February 16, 2006

Respectfully submitted,

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s/ Toni-Ann Citera

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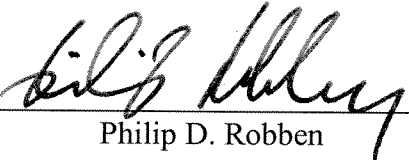
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CERTIFICATE OF SERVICE

I certify that on February 16, 2005, a true and correct copy of the foregoing Dey, Inc.'s and Abbott Laboratories' Objections to the Order of Chief Magistrate Judge Bowler Issued on February 4, 2006 Pursuant to Fed. R. Civ. P. Rule 72(a) was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties. I further certify that on February 16, 2005, a copy was served on counsel for non- parties Tufts Associated Health Plans, Inc, Neighborhood Health Plan, Inc., Fallon Community Health Plan, Inc., and Harvard Pilgrim Healthcare via UPS Overnight Courier.


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